

6111 Broken Sound Parkway NW Boca Raton, FL 33487-3693 (561) 241-9400 Fax (561) 995-5188

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August 18, 1999

Food and Drug Administration Office of Special Nutritionals (HFS-450) Center for Food Safety and Applied Nutrition 200 C Street, SW Washington, DC 20204

Dear Sirs:

Notice is hereby given pursuant to Section 403(r)(6) (21 U.S.C. § 343(r)(6)) of the Federal Food, Drug and Cosmetic Act that Rexall Sundown, Inc. ("Sundown") located at 6111 Broken Sound Parkway, N.W., Boca Raton, Florida 33487 has marketed a dietary supplement under the Thompson brand name bearing the following statement(s) on the label and/or in the labeling:

Horse Chestnut: For leg vein health and circulation. Horse Chestnut seed extract helps to maintain vascular integrity and enhance circulation in the lower legs. Thompson Horse Chestnut is standardized to 18% Escin (54 mg per capsule) and also provides additional beneficial components such as flavones and coumarins for leg vein health. Standardized Horse Chestnut seed extract provides natural support for optimal leg vein health.

The undersigned certifies that the information contained in this notice is complete and accurate and that Sundown has substantiation that the statement is truthful and not misleading. Pursuant to § 101.93 (a)(1), two copies of this notification are enclosed.

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Sincerely,

Deborah Shur Trinker

Dernale Shus John

Vice President of Regulatory Affairs

and Assistant General Counsel

Enclosure

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